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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,669	03/01/2004	Mitta Suresh	5838-01801	7873

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EXAMINER

LANG, AMY T

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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08/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/790,669

Applicant(s)

SURESH ET AL.

Examiner

Amy T. Lang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-28, 53, 75, 97, 116 and 140 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-28, 53, 75, 97, 116 and 140 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/10/2007.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-6, 8-28, 53, 75, 97, 116, and 140 have been considered but are moot in view of the new ground(s) of rejection.

Terminal Disclaimer

2. The terminal disclaimer filed on 23 May 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/235,295 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 97 and 116** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 97 and 116 recite wherein the reinforcing member is positioned within the heart "subsequent to a cardiovascular event prior to substantial deformation." However, this limitation is not supported by the

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specification, which states that the reinforcing member is positioned after a cardiovascular event so that the possibility of ventricular deformation is lessened (see paragraph [0151]). Therefore, the instant specification only supports where ventricular deformation is lessened, not where the apparatus is positioned prior to substantial deformation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1-6, 8-28, 53, and 140** are rejected under 35 U.S.C. 102(e) as being anticipated by Khairkhahan (US 2002/0111647 A1).

With regard to **claims 1, 5, and 15**, Khairkhahan discloses an apparatus comprising a reinforcing element (11) configured to reinforce a portion of an endocardial surface (see entire document; Figure 1). The element (11) is movable between a reduced, first predetermined shape and an expanded, second predetermined shape ([0060]). An adjustment mechanism is utilized to expand the device while in a patient's body so that the reinforcing element is configured to change from the first shape to the second while in a ventricle of the patient's heart ([00796]). The adjustment mechanism

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is further disclosed as a pullwire that is activated by a user ([0076]). Therefore, there inherently exists an infinite number of cross-sectional profiles of the reinforcing element between the fully reduced, first predetermined shape and the fully expanded, second predetermined shape so that user is able to adjust the adjustment mechanism to a third shape.

Although Khaikhahan does not specifically disclose the reinforcing element for use in an endocardial surface of a ventricle, specifically scar tissue, this is an intended use phrase and therefore given minimal patentable weight. The examiner's position is supported by case law, which holds that "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation." *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) and MPEP 2111.02.

With regard to **claim 2**, since Khaikhahan teaches the same apparatus as claimed comprising a reinforcing element having a first and second predetermined shape, it is the examiner's position that the apparatus is configured to inhibit expansion of an average of an endocardial surface over a cardiac cycle of the left or right ventricle.

With regard to **claim 3**, since Khaikhahan teaches the same apparatus as claimed comprising a reinforcing element having a first and second predetermined shape, is the examiner's position that the apparatus is configured to inhibit expansion of an endocardial surface such that normal contraction and expansion during a cardiac cycle of the heart remains substantially unimpeded.

With regard to **claims 4, 6, and 10**, Khairkhahan further discloses the reinforcing element having anchors (195) for attachment to tissue ([0055]; Figure 7A). Therefore, the reinforcing element is configured to releasably attach to the endocardial surface of a ventricle of the heart through the anchors. Furthermore, the anchors clearly overlap the instantly claimed activation mechanism since they are configured to attach the reinforcing member to an endocardial surface.

With regard to **claim 8**, since the adjustment mechanism of Khairkhahan changes the dimension of the reinforcing element, it is therefore configured to change the dimension of a portion of the ventricle.

With regard to **claim 9**, Khairkhahan also teaches a locking mechanism that inhibits movement of the adjustment mechanism ([0076]). Therefore, the locking mechanism of Khairkhahan clearly overlaps the instantly claimed engagement mechanism.

With regard to **claim 11**, the reinforcing element comprises a frame (14) with a porous patch network (15) ([0044], [0047]). Therefore, component 15 clearly overlaps the instantly claimed patch.

With regard to **claim 12**, it is the examiner's position that the second predetermined shape of Khairkhahan substantially emulates the shape and size of a portion of the left ventricle.

With regard to **claims 13 and 14**, the frame (14) of the reinforcing member is comprised of Nitinol ([0046]).

With regard to **claims 16, 26, 28, and 53**, the frame (14) comprises metal spokes (17), which overlap the instantly claimed plurality of conduits ([0044]; Figure 1). Anchors (195) are attached to the spokes and extend distally beyond the conduits ([0055]; [0057]).

With regard to **claim 17**, it is the examiner's position that spokes 17 and 196 overlap the claimed conduits so that Khaikhahan teaches a plurality of conduits with variable length (Figure 1).

With regard to **claims 18 and 19**, Khaikhahan teaches the elongated member as anchors, barbs, hooks, or pins, which are all configured to change shape upon extending beyond the corresponding conduit ([0058]).

With regard to **claims 20 and 21**, it is the examiner's position that the outer rim of frame (14) couples conduits (17) together and overlaps the instantly claimed support element (Figure 1). The outer rim also limits the expansion of the reinforcing element to the second predetermined shape. Furthermore, member 16 couples conduits 196 with conduits 17 and therefore also overlaps the instantly claimed support element (Figure 1).

With regard to **claims 22 and 23**, as shown in Figure 1, the conduits radiate outward from a center region so that the center region (196) couples the conduits together.

With regard to **claims 24 and 25**, the device comprises lumen (322) for positioning a guidewire ([0083]; Figure 19).

With regard to **claim 140**, as shown in Figure 1, the shape of the reinforcing member is similar to a shape and size of a portion of the left ventricle.

7. **Claims 1, 16, and 22** are rejected under 35 U.S.C. 102(e) as being anticipated by Macoviak (US 2002/0143362 A1).

With regard to **claim 1**, Macoviak discloses an apparatus comprising a reinforcing element (114) configured to reinforce a portion of an endocardial surface (see entire document; Figure 2). The element (114) is movable between a reduced, first predetermined shape and an expanded, second predetermined shape ([0038]; Figures 2 and 3). An adjustment mechanism is utilized to expand the device while in a patient's body so that the reinforcing element is configured to change from the first shape to the second while in a ventricle of the patient's heart ([0043]). Therefore, there inherently exists an infinite number of cross-sectional profiles of the reinforcing element between the fully reduced, first predetermined shape and the fully expanded, second predetermined shape so that user is able to adjust the adjustment mechanism to a third shape.

Although Macoviak does not specifically disclose the reinforcing element for use in an endocardial surface of ventricle, this is an intended use phrase and therefore given no patentable weight. The examiner's position is supported by case law, which holds that "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the

preamble is not a claim limitation.” *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) and MPEP 2111.02.

With regard to **claim 16**, the reinforcing element comprises struts (118), which clearly overlap the instantly claimed conduits ([0042]; Figure 2). Shaft (104) is positioned within the conduits and extends distally beyond the conduits as shown in Figure 2 ([0042]). Therefore, shaft (104) clearly overlaps the instantly claimed elongated member.

With regard to **claim 22**, as shown in Figure 2, the conduits (118) radiate from a center region.

8. **Claims 97 and 116** are rejected under 35 U.S.C. 102(e) as being anticipated by Whayne (US 6,887,192 B1).

Whayne discloses the method of placing a reinforcing member within a ventricle of human heart (see entire document; column 4, lines 25-35; Figure 1). The member is positioned subsequent to a cardiovascular event and prior to substantial ventricular deformation (column 3, line 56 through column 4, line 6; column 4, lines 34-36). The reinforcing member is then attached to the heart through anchors or pins, which are releasable attachments (column 6, lines 30-34; column 12, lines 47-51). Once attached, the expansion of an average of an endocardial surface over a cardiac cycle is inhibited (column 4, lines 30-34). Furthermore, the reinforcing member is preshaped to match the ventricle (column 11, lines 20-22). Therefore, a portion of the natural contour of the ventricle is maintained with the reinforcing member.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. **Claims 27 and 75** are rejected under 35 U.S.C. 103(a) as being unpatentable over Macoviak (US 2002/0143362 A1).

Macoviak discloses a reinforcing member having a first and second predetermined shape. The reinforcing member comprises conduits (118) disposed over a shaft (114). The shaft is further disclosed as having a guidewire lumen ([0058]). Although Macoviak does not specifically teach a guidewire within the lumen, it would have been obvious to one of ordinary skill at the time of the invention since it is known in the art for guidewires to be placed within a guidewire lumen and extend distally beyond the device in order to steer/guide the device to the target site.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Lang whose telephone number is (571) 272-9057. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/25/2007

Amy T. Lang

AL



LOAN H. THANH
PRIMARY EXAMINER